## REMARKS

Entry of this Amendment is proper under 37 C.F.R. § 1.116 because the Amendment places the application in condition for allowance for the reasons discussed herein; does not raise any new issue requiring further search and/or consideration; does not present any additional claims; and places the application in better form for an appeal should an appeal be necessary. Entry of the Amendment is thus respectfully requested.

Claims 1-40 are currently pending. Claims 1-10, 21, 24-25 and 29-40 are canceled by way of the present Amendment. Dependent claims 11-20, 22-23 and 28 have been amended to depend off of method claims 26 and 27, so that all claims are now directed to methods of preparing a biologically active composition, as suggested by the Examiner. Thus, no prohibited new matter has been introduced by this Amendment. Applicants reserve the right to pursue in a division or continuation application any subject matter canceled by way of this Amendment without prejudice or disclaimer.

**REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claim 30 stands rejected under 35 U.S.C. §112, second paragraph as being purportedly indefinite. Specifically, claim 30 stands rejected for the recitation of the phrase "type" because it is purportedly unclear as to what is meant by "acrylic or acrylamide type". Claim 30 has been canceled by way of the present Amendment. Thus, Applicants submit that this rejection is mooted.

**REJECTIONS UNDER 35 U.S.C. §§ 102 and 103(a)**

Claims 1-5, 8-14, 17, 22-25, 30 and 33-38 stand rejected under 35 U.S.C. §102(e) and §103 as purportedly anticipated by and unpatentable over Farinas *et al.* (U.S. Patent No. 5,906,830). Farinas *et al.* is cited for purportedly disclosing a method for preparing transthermal drug delivery systems containing super saturated drug reservoirs. Farinas *et al.* also purportedly disclose that an amount of drug molecules dispersed in the reservoir material at a concentration that is greater than the solubility of the drug in the reservoir material at a room temperature to give a supersaturated drug reservoir.

In the interest of expediting prosecution, claims 1-10, 21, 24-25 and 29-40 are canceled by way of this Amendment and claims 11-20, 22-23 and 28 have been amended to depend off of method claims 26 and 27, as suggested by the Examiner. Applicants submit that all of the claims are now directed to methods of preparing a biologically active composition and of preparing the supersaturated state. Thus, the rejections under 35 U.S.C. §§ 102 and 103 are mooted.

**DOUBLE PATENTING**

Claim 1 stands provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1 and 2 of copending U.S. Patent Application No. 09/700,176. As claim 1 has been canceled by way of the present Amendment, Applicants submit that this rejection is mooted.

Claims 1-40 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of copending

U.S. Patent Application No. 09/700,176. Applicants submit a Terminal Disclaimer herewith. Thus, Applicants request that this rejection be withdrawn.

## CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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**Attachment to Amendment and Reply**

**Marked-up Claims 11-20, 22-23 and 28 as follows**

11. (Thrice Amended) The [composition] method according to claim [1] 26, wherein the biologically active agent is added above or around room temperature.

12. (Thrice Amended) The [composition] method according to claim [1] 26, wherein the chemical operations comprise one or more chemical reactions.

13. (Twice Amended) The [composition] method according to claim 12, wherein the chemical reactions comprise etherifying, esterifying, hydrolysis, substitution, addition, elimination, oligomerising or polymerising reactions.

14. (Twice Amended) The [composition] method according to claim 13, wherein the chemical reactions are selected and performed so as to provide optimal delivery rate of the biologically active agent.

15. (Thrice Amended) The [composition] method according to claim [1] 26, wherein the chemical operations involve subjecting the carrier starting substance to a temperature of from around -50°C to around 300°C.

16. (Thrice Amended) The [composition] method according to claim [1] 26, wherein the chemical operations are conducted for a time period of from 1 minute to 6 months.

17. (Thrice Amended) The [composition] method according to claim [1] 26, wherein the carrier starting substance, or mixture of two or more difference carrier starting substances, is selected from the group consisting of monomers, acids, alcohols, ketones, aldehydes, amines, amides, anhydrides, lactides, glycolides, saccharides, acrylic or acrylamide compounds, monomers of PEO-diacrylate, cyanoacrylate, acrylate saccharides, acrylate lactate, acrylate glycolate, isocyanates, ethylene oxide, propylene oxide, pyrrolidone, PEO-diacrylate, ethylene-vinyl acetate, monomers of organic siloxanes, and oligomers, polymers and prepolymers thereof.

18. (Twice Amended) The [composition] method according to claim 17, wherein the acid is a monomeric acid and the alcohol is a monomeric alcohol, wherein the non-crystalline matrix comprises an ester or polyester thereof.

19. (Twice Amended) The [composition] method according to claim 18, wherein the monomeric acid is citric acid.

20. (Thrice Amended) The [composition] method according to claim 18, wherein the monomeric alcohol is propylene glycol.

22. (Thrice Amended) The [composition] method according to claim [1] 26, wherein the biologically active agent is a pharmaceutically active agent.

23. (Thrice Amended) The [composition] method according to claim 22, wherein the pharmaceutically active agent is selected from the group consisting of guanosides, corticosteroids, psychopharmaceutical hormones, oxicams, peptides, proteins, antibiotics, antivirals, antimicrobials, anticancer agents, antifungals, oestrogens, antiinflammatory agents, neuroleptic agents, melanocyte stimulants and gland stimulants and agents with an effect on mast cell secretion.

28. (Twice Amended) The [composition] method according to claim [2] 26, wherein the supersaturation is the result of chemical operations such that the degree of dissociation, aggregation or degree of protonation of the biologically active agent is different from the degree of dissociation, aggregation or degree of protonation of the agent in the carrier starting substance.